

How To Process Or Manufacture Food For “Commercial” Sales

Kentucky’s Home-based Processor Registration and Home-based Microprocessor Certification programs provide a unique opportunity for farmers to “test the waters” in terms of value-added product acceptability and sales without having to assume the level of financial risk generally associated with “commercial” food sales. However, if you are pleased with the sales of your home-based processor or home-based microprocessor products, you may be ready to take that next step into “commercial” food production.

A particular advantage of “going commercial” is that your market opportunity is greatly expanded. Remember, the sales and marketing of products produced under the home-based processing programs are restricted to KDA-listed farmer’s markets, Kentucky Farm Bureau certified roadside stands, and on-farm sales locations. On the other hand, food products produced under a valid “commercial” permit (as opposed to a home-processing registration or certification) can be marketed in a much broader arena that includes restaurants, grocery stores, supermarkets, and gift shops, in addition to the three locations approved for home-based processed foods.

A List of Things You Need To Be Aware of Regarding the Manufacture of Packaged Food For “Commercial” Sales

A. These are the general, prerequisite structural and fixture requirements necessary for the issuance of a commercial permit to manufacture food in Kentucky:

- (1) The submittal of construction plans, through your local health department, for new or renovated facilities
- (2) An insect/rodent-proof facility that is constructed of smooth, non-absorbent and easily cleanable materials
- (3) If not connected to a municipal utility—an approved water supply
- (4) If not connected to a municipal utility—an approved onsite (septic) waste disposal system
- (5) A hand wash lavatory in the food preparation/utensil wash area(s)
- (6) A three-compartment utensil wash sink with drain boards
- (7) A utility/mop sink
- (8) Approved employee restroom facilities

B. In addition to the structural and fixture requirements noted above, there may be other product-specific equipment, training, and record-keeping requirements as well. For instance, “commercial” juice processors, fish processors, and “commercial” manufacturers of acidified or low-acid foods (such as pressure-canned vegetables, sugarless, and non-fruit jams/jellies) will have to meet additional state and federal food-safety stipulations. The Kentucky Food Safety Branch can provide additional information and insight as to product-specific requirements and can provide you with a complete informational packet on the requirements for “commercial” food manufacturing. The Food Safety Branch may be reached at (502) 564-7181.

C. Also, for foods sold in packaged form, product labels must be reviewed by the Food Safety Branch prior to the marketing of manufactured items. Product labels should be directed to the attention of Annhall Norris. Ms. Norris can also answer questions regarding nutritional facts panel labeling requirements and exemptions for small producers. Ms. Norris may be reached by telephone at (502) 564-7181, extension 3683.

D. You should also be aware that, as a result of new Food and Drug Administration (FDA) regulations designed to enhance food safety and security, non-exempt domestic and foreign food facilities that manufacture, process, pack or hold food for human or animal consumption in the United States are required to register with FDA. This is a fairly simple, online computer registration process. Should you have questions pertaining to the registration requirement, please contact (800) 216-7331 or (301) 575-0156. Additional information pertaining to the registration process can be found at the following internet address: www.cfsan.fda.gov/~furl/ovffreg.html.

E. With any business venture, including “commercial” food manufacturing, there are certainly financial risks and expenses. However, producing a value-added food product under a “commercial” permit may not be as difficult and cost-prohibitive as one might assume.

Though a residential kitchen cannot be utilized for “commercial” food manufacturing and processing, you may still be able to conduct certain “commercial” manufacturing and processing activities from your home, if you wish to convert an area into a small food manufacturing operation. For instance, a number of small processors across the state have converted a portion of their home, such as a garage or basement room, into a dedicated “commercial” kitchen that is used for the production of “commercial” jams, jellies, candies, cakes, breads, and other baked goods. In addition to meeting the requirements noted above, this will necessitate that your dedicated “commercial” kitchen be completely separated from the domestic kitchen and living quarters of your home. Solid walls and/or self-closing doors would generally be considered acceptable for this purpose.

Three other options you may wish to consider if you are interested in “going commercial” are as follows:

Option 1 - Use of Existing Facility:

To avoid new construction or renovation of a portion of your home, you may wish to use an existing permitted kitchen or find an existing kitchen in your community (such as a church kitchen or community civic group kitchen) that would meet the structural, equipment, construction, and the water and waste disposal requirements required for the issuance of a “commercial” permit. In either case, as part of your permit application process, your food safety inspector will typically require that you submit a written agreement which verifies that the property owner has granted you access and permission to utilize the facility, and that all of your products will be manufactured in that establishment during periods when the establishment itself is not in operation. In

addition, your food safety inspector will need to review your proposed manufacturing process, standard operating procedures, and, in some cases, product shelf stability documentation.

Option 2 - Custom Manufacturing by Permitted Facility:

You may wish to have your food product manufactured for you by an existing, permitted food processing facility. Under this option, the firm would typically utilize your recipe to manufacture the product and would apply your label to the finished product. Should you select this option, you would not be required to obtain a permit to operate as a food processing establishment, however, you may be required to obtain a food storage warehouse permit if your product is stored at a location (such as your residence) other than the site where it was manufactured. If you intend to warehouse food products at home, you will need to contact the Food Safety Branch for a determination of whether it will be necessary for you to obtain a warehouse permit. Remember, if you intend to store manufactured food products at your residence that are intended to be sold retail or wholesale, it will be necessary for you to find a suitable location so that these items are stored separate and apart from residential or personal items.

Option 3 – New Construction/Renovation:

Under this option, there are a number of steps to consider.

First - If you plan to move into an existing building that previously served as a restaurant or food processing establishment, contact the Food Safety Branch office, or area food manufacturing inspector, to determine if what you are proposing can be done in the structure without a lot of costly renovations. Your area food inspector will be glad to meet with you for a consultation as well as conduct a “courtesy” inspection of the facility as a means to provide you with an accurate assessment of what needs to be completed so that the structure meets the requirements for permit issuance. Also, if you plan to move into an existing structure that has never been utilized as a restaurant or food processing establishment, or if you intend to build a new building, you will need to contact your local health department as well as the Food Safety Branch, prior to construction, for step by step guidance, including plan review. The state plumbing inspector, usually located in your county health department, will also be able to answer any questions you might have regarding this process.

Second - Put your facility floor plans (including plumbing schematic) on paper and contact your local health department environmental services office for directions regarding the plan review and submittal process. Remember, any location without municipal water or municipal sewer service will also have to comply with additional state/local stipulations pertaining to water/waste treatment and be able to provide documentation of approval to the pertinent state or local health department representatives.

Third – Determine who the area food inspector is for your region of the state. The Food Safety Branch can provide you with this information. You will then provide your area food inspector with information relating to your product, such as product formulation,

ingredients, manufacturing process, cooking, holding and storage times and temperatures, and intended product distribution. At this point you will also want to ensure that your proposed product label meets all state and federal labeling requirements. Ms. Annhall Norris of the Food Safety Branch (502-564-7181, extension 3683) can assist you with this process. Your area food manufacturing inspector will want to make sure you know how to safely manufacture, store, distribute and label your food products.

Fourth – At this point, you may be ready to apply for a permit to operate and pay the applicable permit fees. This step will be done through your area food manufacturing inspector. In many cases, this step will occur at the same time as your “opening” inspection, discussed below.

Permits expire on December 31st from the date issued. Each year, prior to the permit expiration date, a renewal notice is mailed to current permit holders. If an individual wishes to renew their permit, they will return the notice, with the required fees, to the Department for Public Health-- Food Safety Branch. The permit fee schedule for food manufacturing and food processing establishments and food storage warehouses is based on square footage as follows:

0 – 1,000 Square Feet	\$ 75
1,0001 - 5,000 Square Feet	\$ 85
5,001 – 30,000 Square Feet	\$147
30,001 – 40,000 Square Feet	\$275
40,001 or more Square Feet	\$290

Fifth - Now you may be ready to request your opening inspection by your area food manufacturing inspector. The opening inspection is typically conducted after your plumbing is inspected. The plumbing inspector will conduct the first inspection to make sure any plumbing changes or additions have been done by a licensed plumber and have been installed correctly. The plumbing inspector will place a sticker in a particular location (usually on your water heater) if the plumbing passes inspection. Once your plumbing has been approved, your area food inspector will conduct your opening inspection. Once you pass the opening inspection, you will receive a permit to operate. This permit will remain valid as long as your permit is renewed yearly and your establishment operates in conjunction with applicable food safety laws and regulations.

For more information about the permit application process, please contact the Kentucky Department for Public Health's Food Safety Branch at (502) 564-7181. An informational packet is available which contains the following documents:

- A copy of Kentucky's Food Drug and Cosmetic Act
- A copy of Kentucky's Food Packaging and Labeling Regulation
- A "Guide to the Labeling of Food Products in Kentucky"
- Some general information on food manufacturing
- *Food Security Preventive Measures Guidance* document for Food Producers, Processors, and Transporters
- A fact sheet for "How To Process or Manufacture Food For Sale"
- The Publication "What you Need to Know About Facility Registration"
- Other product-specific information

Product-Specific Considerations for Food Products Containing Meat/Poultry:

The guidelines above describe the general process for obtaining a permit-to-operate in order to manufacture FDA-regulated foods in Kentucky. The above steps, however, do not apply to USDA-regulated products, such as most meat and poultry processing and manufactured food products containing meat and poultry.

In general, the United States Department of Agriculture (USDA) has jurisdiction over the commercial manufacture or processing of food products containing meat and/or poultry. The USDA is a federal agency that has offices in Kentucky. Depending upon the specifics of your manufacturing process, including the source of the meat products to be utilized, how your final food product is manufactured, and how you plan to market your product, USDA may retain sole regulatory jurisdiction over your manufacturing process. In order to be sold wholesale to restaurants or grocery outlets in Kentucky, processed foods under USDA jurisdiction which contain meat or poultry must bear the USDA mark of inspection.

Typically, food products containing 3% or more beef, or 2% or more poultry fall under the regulatory jurisdiction of USDA. Should your intentions include the manufacture of products containing meat/poultry, this is to advise that you first contact the USDA District office, located in Raleigh, North Carolina (919-844-8400) and enlist the agency's assistance in determining their jurisdiction over your proposed product. At this time you will want to explain your plans to USDA and inquire about the necessity for obtaining a "Grant of Federal Inspection." Dr. Chet Miller (502-797-6119) is the USDA Frontline Supervisor for the Central Kentucky area. USDA's Technical Service Center (402-221-7400) in Omaha, Nebraska should also be able to address additional questions you may have. In the event you are advised that your proposed product falls outside of USDA jurisdiction, the Food Safety Branch will typically require that you obtain from USDA a "letter of release" from USDA jurisdiction and that a copy of this document be submitted with your permit application.

Questions concerning specifics of the USDA inspection process should be directed to the following address:

USDA, FSIS, OFFICE OF FIELD OPERATIONS
Raleigh Regional Office
6020 Six Forks Road
Raleigh, NC 27609
(919) 844-8400